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09/132,593	08/11/1998	ASGEIR SAEBO	21440/9015	9659
23535	7590	11/04/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

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**GROUP 1600**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/132,593  
Filing Date: August 11, 1998  
Appellant(s): SAEBO ET AL.

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J. Mitchell Jones  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed August 18, 2004.

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**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Appellant's brief includes a statement that claims 1-6 and 8; stand or fall together.

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) *Prior Art of Record***

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The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

US Patent 5,554,646	Cook et al.	September 10, 1996
US Patent 3,162,658	Baltes et al.	December 22, 1964
WO 97/18320	Cain et al.	May 22, 1997

Chin et al. "Dietary sources of conjugated dienoic isomers of linoleic acid, a newly recognized class of anticarcinogens," Journal of food composition and analysis, 1992, Vol. 5, pages 185-197.

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a)

These rejections are fully set forth in prior office action, mailed July 24, 2004, and reiterated in full below.

**(11) Response to Argument**

1. Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,554,646) in view of applicants' disclosure at page 11, line 13-25 in the specification, Cain et al. (WO 97/18320), and Chin et al. (IDS, November 23, 1999), in further view of Baltes et al. (US Patent 3,162,658).

Cook et al teach an active form of conjugated linoleic acid, i.e., 10,12-octadecadienoic acid and 9,11-octadecadienoic acid, which includes esters, salts and free acids of conjugated linoleic acid. See, particularly, column 1 lines 65-67, column 2, line 1 and column 4, lines 1-9.

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The conjugated linoleic acid may be obtained through isomerization of safflower oil. See column 2, lines 12-45. Cook et al. further teach a food product comprising said active form of conjugated linoleic acid. See, particularly, column 1, lines 39-60 and examples 1-4. The feeding may also comprise phosphatides. See, column 5, line 47. '646 also teach a safe and effective method for reducing body fat in animal by administering said food product. See particularly, the abstract. C9, t11- and t10, c12- isomer are the predominantly major isomers of the conjugated linoleic acid active form of Cook'646. See, particularly, column 4, lines 50-55.

Cook et al. do not teach expressly the conjugated linoleic acid active form further comprising the regio isomers 8,10- and an 11,13- octadecadienoic acid derivative, or specify the particular amounts of each 9, 11 and 10, 12 isomers of octadecadienoic acids, or the amount of phosphatides.

However, since the preferred amounts of the regio isomers 8,10- and an 11,13- octadecadienoic acid derivative in the claimed invention are limited to less than 2 percent, this amount includes zero percent of the regio isomers as disclosed by Cook. Thus, Cook's teachings meet this limitation. Chin et al. teach that it is known that c9; t11- conjugated linoleic acid isomer is an active form of conjugated linoleic acid. See, particularly, page 185, the abstract. Regarding the limitation of the particularly amount of phosphatidyl residue, note as disclosed at page 11, line 13-25 in the specification, it is known that safflower oil contains about 0.4-1.0 % of phosphatidyl residue. It would have been reasonably expected that isomerized Safflower oil (also is the starting material herein) containing phosphatidyl residue. Cain et al. further teaches a CLA composition made from sunflower oil for food additive contains 48.9 % of c9, t11, 51.1 % of t10,

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c12 linoleic acid or their esters. See, particularly, examples 6 at page 16, and example 18 at page 36, and claim 7. The composition is suitable for food products. See, particularly, claim 14.

Therefore it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9, t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester, such as those disclosed by Cain et al., and employ the mixture in food products.

A person of ordinary skill in the art would have been motivated to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9, t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester and employ the mixture in food products because 8,10- and 11,13- octadecadienoic esters are known not to be required in the active form of conjugated linoleic acid and the c9, t11 and t10, c12 isomers are known to be the preferred isomers in food products. Further, alkyl ester of c9, t11- and t10, c12-octadecadienoic acids are known to be similarly useful as the free acid and the other esters. Further, Baltes et al. teach that employment of low alkali alcoholate as catalysts for isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers is known. See, column 2, lines 16-35, column 5, lines 5-21, column 8, lines 22-67, and the claims. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made, to obtain conjugated linoleic acid from safflower oil through the isomerization process taught by Baltes.

Appellants traverse the rejections on the ground that Cook et al. and Cain et al. either incorrectly, or incompletely report the results about the contents of the CLA compositions.

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Appellants assert that the CLA compositions taught by Cook et al. or Cain et al. would (inherently) have more than 2% of 8,10- and 11,13- octadecadienoic ester. In supporting his position, appellant filed a 1.132 declaration showing a repeated experiment according to Cain et al. results in a CLA composition containing more than two percent of trans, trans, 8,10- and 11,13- octadecadienoic isomers. Appellant also cites Sugano et al. (Lipids 33 (5) :521-527, 1998), and asserts that Sugano et al. employed a method similar to those of Cain et al. yield a CLA composition containing more than two percent of trans, trans, 8,10- and 11,13- octadecadienoic isomers. All the evidences and arguments presented by appellants have been fully considered, but have been found unpersuasive.

2. Particularly, as to the 1.132 declaration filed by the appellant, the examiner maintains his position stated in the office action mailed December 31, 2002 (paper No. 34): "the declaration fails to establish the fact that the conjugated linoleic acid disclosed by Cook or Cain as recited in the prior office action contains more than 2% of the isomers identified in claim 1 herein. Particularly, applicant generated data, proffered to obviate prior art teachings, lacks the probative force accorded data generated by independent, disinterested parties. It is well settled patent law "that it is not a difficult matter to carry out a process in such a fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight" In re Michalek, 74 USPQ 108, at 109 citing Bullard Company et al v. Coe, 147 F.2d. 568, 64 USPQ 359." Applicants have argued that CLA compounds, including those disclosed in the cited prior art, inherently comprising more than 2% of trans, trans, 8, 10 and 11, 13 octadecadienoic acids or derivatives. The arguments are not convincing. Particularly, the presence of trans trans isomers is well known in the art, and is

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acknowledged by Cain (page 1, lines 15-25). However, Cain et al. do not disclose the presence of trans isomers in their CLA composition. The examiner is not convinced by the assumption that Cain et al. cannot detect the trans trans isomers, or simply ignore the presence of the isomers. The evidence provided with the declaration has been fully evaluated against the cited reference. Appellant provided his own results contrary to the references, making assumption without factual support. The evidences provided by appellant fail to prove that, as a matter of fact, the data reported by Cain et al. or Cook et al. is either incorrect or incomplete.

3. Appellant has argued that *In re Michalek* does not applied to the fact of present case; evidence presented by applicants has not been considered. Particularly, appellants argued that *In re Michalek* is a decision more than 50 years old and is conflict with current case law and PTO practice. The examiner fails to see any conflict between the *In re Michalek* decision and current case law or current PTO practice.

Appellant asserts that the office refuses to consider the evidence presented by appellant. This is not true. Appellant is confusing “persuasive” with “considered” As stated in prior office action, all the arguments presented by applicants, including the evidence submitted with the declaration, have been fully considered, but are found not persuasive. The examiner has not ignored appellant’s evidences. All the facts, including appellant’s evidences have been fully evaluated. When applicants’ evidence is not consistent with the teaching from prior art, *In re Michalek* is properly applied. The examiner fails to see any conflict between the *In re Michalek* decision and current case law or current PTO practice.

Appellant further argues that *In re Michalek* is limited to its particular fact, which is not applicable to the instant situation. Particularly, appellant argues that in Michalek characterizes



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the evidence as a failure, while appellant's declaration does not show Cain et al. or Cook et al. fail to produce CLA. The examiner disagrees. The declaration herein and the affidavit in Michalek are similar in that both try to show the prior arts lack a feature which would make the claimed invention patentably distinct from the prior art. The examiner does not consider the data presented in the declaration incorrect. But the data is insufficient to prove the reported data in Cain et al or Cook et al are incorrect or incomplete. Appellant has complained that the office has not analyzed the fact provided by appellant. It is noted that the examiner could not give more detailed analysis to the data presented in the declaration since the declaration merely states that appellant has repeated the experiments in Cain et al. It is assumed that appellant just simply duplicated an experiment disclosed by Cain et al. In the instant case, like in re Michalek, more extensive experiments might have produced a different result.

4. In the declaration, appellant's assertion that the reported data about the CLA composition is either incorrect or incomplete based on two assumptions: "1) method for the analysis of CLA composition in 1996 were *rather crude* and 2) Cain *may* have simply chosen not to include non active isomer when reporting their results (page two of the declaration, emphasis added)." As to the second assumption, note Cain et al. have recognized the existence of the trans, trans, 8,10- and 11,13- octadecadienoic isomers. (page 1, lines 15-25). Cain is not silent about the isomers identified herein, and therefore is not likely to simply ignore the presence of those isomers. Regarding the first assumption, note, and GC method is a well-developed analytical method even in 1996. Method for CLA analysis may be further optimized later. However, there is no evidence showing GC method in 1996 were crude enough to miss those well-recognized CLA isomers.

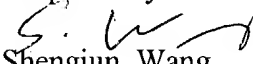
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5. Appellant also argues that Cain et al. or Cook et al. do not clearly define conjugated linoleic acid (CLA) to include those isomers herein identified. Note, neither Cain et al. or Cook et al. exclusively defines conjugated linoleic acid as C9,t11 and t10,c12 isomers only. By its plain meaning, "conjugated linoleic acids" would include all octadecadienoic acids with conjugated double bonds, including those herein defined.
6. As to the reference of Sugano et al., it is noted that appellant has recognized that the procedure disclosed in Sugano et al. is merely similar to, but not the same as, that disclosed in Cain et al. Many of the conditions have not been fully described, such as the way for heating or cooling, acid used to acidify the reaction mixture, the way to extract the product from the reaction mixture, the impurity in the employed materials, etc. all those conditions might have well affected the final product. Having seen the results in Cain et al. and Sugano et al, one of ordinary skill in the art would not come to the conclusion that one of the results must be incorrect or incomplete, and/or, make a judgment on which data is correct. Further, it is noted that example 6 in Cain et al. employs sunflower oil as the source of linoleic acid, which was not used by Sugano et al.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

  
Shengjun Wang

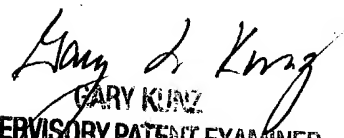
Primary Examiner  
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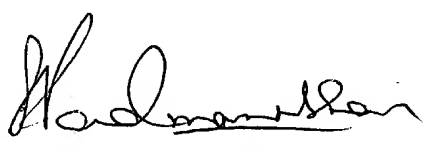
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November 1, 2004

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